Docket No.: 01-11 US

## <u>REMARKS</u>

This is a response to the Notice of Non-Complaint Amendment under 37 CFR 1.121 mailed December 02, 2003 and the Office Action mailed September 24, 2003.

In the Notice of Non-Complaint the Legal Instruments Examiner stated that the complete listing of all of the claims was not present in the response to the Office Action of September 24, 2003. The Applicants corrected the omission and introduced claims 1-20 that were canceled when the RCE submission has been made.

To follow is a response to the Office Action of September 24, 2003.

Claims 21-58 have been rejected by the Examiner under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. Specifically, the Examiner has stated that the terminology "second hollow container" is unclear. In response thereto, the Applicants have amended independent claims 21, 31, 42, 48 and 54 as recommended by the Examiner to overcome the rejection under 35 USC 112, second paragraph.

In addition, claim 36 has been amended to add a part of the claim inadvertently omitted. No new matter is added by the present amendment.

Claims 21-56 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over WO 97/25606 to Rasmussen, et al. in view of U.S. 6,164,144 to Berg.

In this rejection, the Examiner has stated that Rasmussen, et al. teaches a device and method for liquid-liquid micro-extraction and the method comprises providing a carrier, modifying the carrier, immobilizing a solvent on the carrier surface, contacting the carrier with the sample, concentrating and fixing the analyte of interest to the solvent and analyzing the carrier. The Examiner also states that Rasmussen teaches a fibre carrier.

However, the Examiner acknowledges that Rasmussen, et al. does not specifically teach the use of a hollow fibre or an acidified acceptor solution. The Examiner states that Berg teaches methods and device for a solid phase micro-extraction (SPME). The reference teaches the use of a hollow fibre with SPME wherein the fibre access a "sponge". In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of the sample in the vial.

The Examiner concludes it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a magnetic stirring bar, hollow fibre, and an

acidified acceptor solution with the invention of Rasmussen, et al.

The Examiner has agreed that neither Rasmussen or Berg teach LLME or LLLME where the analyte passes through the membrane wall and is collected on an opposite side. However, the Examiner has maintained that such arrangement would have been obvious to one of ordinary skill in the art at the time the invention was made.

As earlier pointed out by the Applicants, each of the references is related to structure and method for a separation of an analyte using a surface phenomenon. As claimed, the present invention includes a second container, that is hollow, which includes a membrane wall with fibre pores permeable by the analyte and means for enhancing transport of the analyte from the sample through the membrane wall and into the acceptor solution.

This must be contrasted with the surface phenomenon of the Rasmussen, et al. and Berg references. In fact, it has been held that a surface does not constitute a layer with interconnected pores and that such a surface would not lead a person of ordinary skill in the art to the use of a membrane wall with fibre pores. See <u>American Standard, Inc. v. Pfizer, Inc.</u>, 14 USPQ 2d 1673, 1713 (Dist. Ct. D. Del. 1989) (copy enclosed).

The Applicants submit that a prima facie case has not been made by the Examiner. The Examiner has failed to adequately explain why the skill routineer in this art would have been motivated to use the hollow porous fibre claimed in the present application. Ortho Kinetics, Inc. v. Safety Travel Chairs, Inc., 1 USPQ 2d 1081 (Fed. Cir. 1986).

The Examiner has present no supporting explanation or evidence why it would have been obvious to use the particular hollow porous membrane presently claimed. Ex parte Marinaccio, 10 USPQ 2d 1716, 1717 (PTO Bd. Pat. App. Int. 1989). (Copy enclosed)

The Applicants further submit that the Examiner is basically relying on general knowledge to negate patentability on the ground of obviousness and this necessitates an articulation of that knowledge in order to place it on record since Examiners are presumed to act from the view point of persons of ordinary skill in the art in finding relevant facts accessing significance of prior art and making ultimate determination of obviousness issue. A failure to do so is not consistent with either effective administration, procedure or effective judicial review and accordingly conclusionary statements when dealing with particular combinations of the prior art and specific claims must set forth the rational on which it relies. In re Lee, 61 USPQ 2d 1430,

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1435 (CAFC 2002).

In conclusion, in view of the arguments hereinabove set forth, the Applicants submit that a prima facie case of obviousness has not been made in the rejection of claims 21-58 under 35 USC 103(a) on the basis of the Rasmussen, et al. and Berg references.

In view of the arguments hereinabove set forth and amendment to the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,

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